No. 01-188

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Petitioner,

v.

KEVIN CONCANNON, COMMISSIONER, MAINE DEPARTMENT OF HEALTH, *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the First Circuit

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BRIEF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES, COUNCIL OF STATE GOVERNMENTS, NATIONAL LEAGUE OF CITIES, U.S. CONFERENCE OF MAYORS, INTERNATIONAL CITY/COUNTY MANAGEMENT ASSOCIATION, AND NATIONAL ASSOCIATION OF COUNTIES AS *AMICI CURIAE* SUPPORTING RESPONDENTS

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QUESTIONS PRESENTED

1. Whether the Federal Medicaid statute impliedly preempts Maine from using its prior authorization authority to negotiate discounts on behalf of its citizens who lack prescription drug coverage.

2. Whether Maine Rx violates the dormant Commerce Clause.

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INTEREST OF THE *AMICI CURIAE*

Amici are organizations whose members include state, county, and municipal governments and officials throughout the United States.[1] *Amici* have a compelling interest in legal issues that affect state and local governments.

The Maine Legislature enacted the Maine Rx program "to enable the State to act as a pharmacy benefit manager [PBM] in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare." 22 Me. Rev. Stat. Ann. § 2681.1 (Pet. App. 86a). The statute directs Maine's Commissioner of Human Services to negotiate rebate agreements with drug manufacturers, which are used to reduce retail prices for the uninsured, much as private PBMs negotiate with manufacturers on behalf of the insurance plans they represent. *See id.* § 2681.4.

The court of appeals held that Maine Rx's use of Medicaid prior authorization authority does not conflict with the Medicaid statute. The court also held that the program does not violate the dormant commerce clause. Affirmance of these holdings is necessary to preserve the States' authority to create innovative programs to make necessary prescription drugs more affordable to their citizens who lack insurance.

Because of the importance of this issue to *amici* and their members, this brief is submitted to assist the Court in its resolution of the case.

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[1] The parties have consented to the filing of this *amicus* brief and their letters of consent have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity other than *amici* or their members made a monetary contribution toward its preparation and submission.

STATEMENT

1. Prescription drugs have become increasingly important in the treatment of illnesses and chronic conditions. From 1997 through 2001, retail spending on prescription drugs increased at annualized rates of 17 to 18 percent, with total spending rising from $78.9 to $154.5 billion. *See* National Institute for Health Care Management, *Prescription Drug Expenditures In 2001: Another Year of Escalating Costs* 2 (2002). Moreover, "[p]rescription drug expenditures are forecast to continue to rise faster than any other medical service sector over the next decade." *Id.* at 3. HHS estimates that by 2008, prescription drug spending will rise to $243 billion dollars. *See* U.S. Department of Health & Human Services, *Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices* 85 (2000) (Table 2-29); *see also* William H. von Oehsen, III, *et al.*, Public Health Institute/Pharmaceuticals & Indigent Care Program, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities* 2 (2001).

For an individual consumer, the average retail price of a prescription drug rose from $45.27 to $49.84 between 2000 and 2001, an increase of more than ten percent. *See Prescription Drug Expenditures*, *supra*, at 8. Among the fifty drugs with the greatest sales (most of which are patent-protected products), the average price of a prescription rose from $65.79 to $71.56, an 8.8 percent increase. *Id.* at 13.

Prices are even higher for most drugs that are recognized as the leaders in their therapeutic class. For example, in 2001 anti-cholesterol drugs such as Lipitor and Zocor had an average price per prescription of $84.96 and $120.82. *Id.* The anti-ulcerants Prilosec and Prevacid had an average price of $143.68 and $133.20. *Id.* The arthritis treatments Celebrex and Vioxx had an average price of $ 97.32 and $ 85.44. *Id.*

While these figures represent average prices, at the retail level there is a great disparity between prices paid by cash

customers and those who either have insurance or are enrolled in Medicaid or other government-assisted programs. This is due in large part to the differences in bargaining power between the purchaser(s) and both retailers and manufacturers.

For example, cash customers who either pay out of their own pocket or have indemnity-type insurance "generally pay the highest prices for drugs because they lack the opportunity, let alone the bargaining power, to negotiate discounts from either the retail pharmacy or the manufacturer." *See Pharmaceutical Discounts*, *supra*, at 4. These customers, who comprise approximately 25 percent of the market, *see id.*, "generally pay at or above . . . the manufacturer's list price," which is also known as the average wholesale price or AWP. *Id.* at i (Executive Summary); *see also Report to the President*, *supra*, at 99 (figure 3-1).

In contrast, the largest portion of the retail drug market (approximately 65%) involves consumers who belong to a plan managed by a pharmacy benefit manager (PBM), whether a private insurance plan, managed care plan, or a self-insured company plan. *See Pharmaceutical Discounts*, *supra*, at 4; *Report to the President*, *supra*, at 99. Because a PBM "manage[s] . . . drug benefit[s] for a large number of individuals," it has substantial bargaining power and "can negotiate discounts . . . from the manufacturer and from the retail pharmacy." *Report to the President*, *supra*, at 103. Accordingly, manufacturer rebates can range from 5 percent to as much as 35 percent on some drugs. *See id.* at 105.

"PBMs that operate under contract to an insurer or self-insured employer are required to pass on most of the rebates" to their customers. *Report to the President*, at 105. Thus, "PBM customers typically pay less than a drug's average manufacturer's price (AMP)—which is about 20 percent below AWP—and [sometimes] as low as 40 percent below AWP." *Pharmaceutical Discounts*, *supra*, at i (Executive

Summary).[2] Thus, the same drug that costs a cash customer $52, will cost a PBM's customers (the consumer and the plan) an estimated $ 30 to $ 44. *See Report to the President*, *supra*, at 98 (Table 3-1); *see also Pharmaceutical Discounts*, *supra*, at 5 (Chart 3).

Those who lack drug coverage and are charged full retail prices are far more likely to forgo filling a prescription. According to an HHS study of the non-Medicare population in 1996, while 70.0 percent of those with coverage filled at least one prescription, only 33.9 percent of those who lacked coverage did so. *See Report to the President*, *supra*, at 45 (Table 2-2). Moreover, the average number of prescriptions filled was 6.8 for those with coverage but only 2.02 for those without. *See id.* Among persons in fair or poor health, those with coverage filled an average of 25.11 and 37.86 prescriptions respectively. *See id.* at 58 (Table 2-11). In contrast, those without coverage in fair or poor health filled an average of 16.80 and 25.80 prescriptions respectively. *See id.*[3]

A 1997 study by the Centers for Disease Control found that among those who lacked health insurance, 35.7 percent of those in fair health and 60.5 percent of those in poor health reported that they had not filled a prescription because of its cost. *See id.* at 80 (Table 2-27). Moreover, even among

[2] The average manufacturer price (AMP) is the price paid by wholesalers to the manufacturer. *See Pharmaceutical Discounts*, at 5. AWP is the manufacturer' suggested list price for the sale by the wholesaler to the retail pharmacy. *Id.* Manufacturers typically sell to wholesalers at "about 20 percent below the list price or AWP," *Report to the President*, *supra*, at 101, and wholesalers frequently sell to retailers at prices below AWP. *See id.* at 4; *see also Pharmaceutical Discounts*, *supra*, at 5.

[3] For persons in good health, there was also a large difference in prescriptions filled. Those with coverage filled an average of 14.59 prescriptions, those without filled an average of 8.09. *See Report to the President*, *supra*, at 58 (Table 2-11).

those with incomes in excess of 400 percent of the federal poverty line, 13.7 percent of those without insurance reported that they did not fill a prescription because of its cost. *See id.*

2. "[T]o reduce prescription drug prices" for its citizens who lack drug coverage, Maine adopted the Maine Rx Program. 22 Me. Rev. Stat. Ann. § 2681 (Pet. App. 86a). Finding "that affordability is critical in providing access to prescription drugs for Maine residents," the Maine Legislature enacted the program "to enable the State to act as a pharmacy benefit manager in order to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare." *Id.* § 2681.1. The statute directs Maine's Commissioner of Human Services to negotiate rebate agreements with drug manufacturers much as private PBMs negotiate with manufacturers on behalf of the insurance plans they represent. *See id.* § 2681.4 (Pet. App. 87a). When a manufacturer does not enter into a rebate agreement, the Maine Rx statute directs that the Department of Human Services "shall impose prior authorization requirements in the Medicaid program . . . as permitted by law, for the dispensing of prescription drugs by those manufacturers." *Id.* § 2681.7 (Pet. App. 90a).[4]

Under the proposed rules of the Maine Rx program, the State's Department of Human Services will review the drugs of non-participating manufacturers to determine "the clinical

[4] Under the federal Medicaid statute, drug manufacturers must, as a condition of coverage of their drugs, agree to provide rebates on drugs purchased by the Department of Veterans Affairs, the Department of Defense, the Coast Guard, the Public Health Service, and the Indian Health Service. *See* 42 U.S.C. § 1396r-8(a)(1) & (6); *see also* 38 U.S.C. § 8126. The federal Medicaid statute further requires that manufacturers, as a condition of coverage, agree to discounts to various health care entities as defined by 42 U.S.C. § 256b(a)(4). *See* 42 U.S.C. § 1396r-8(a)(1) & (5).

appropriateness of prior authorization for those drugs under the Medicaid Program." J.A. 320. The final determination will be made, however, by the State's Medicaid Drug Utilization Review Committee, a board comprised of licensed physicians and pharmacists, which must make its decision "in accordance with federal and state law." *See id.*, *see also id.* at 149 (affidavit of Timothy S. Clifford, M.D., at ¶ 9). The regulations further require that "[i]n all instances, Medicaid recipients shall be assured access to all medically necessary outpatient drugs." *Id.* at 320 (Maine Rx proposed rules). Finally, the State "will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturer[] participates in [the] Maine Rx Program by entering into rebate agreements." *Id.* at 149 (Clifford affidavit at ¶9).

SUMMARY OF ARGUMENT

1. The Maine Rx program's use of Medicaid prior authorization authority does not conflict with the Medicaid statute because it does not burden Medicaid patients and physicians. Maine's rule complies with the requirements of 42 U.S.C. § 1396r-8(d)(1)(A). Maine physicians are very familiar with the prior authorization rule as more than 400 drugs are already subject to Medicaid prior authorization. Moreover, the rule does not unreasonably interfere with physicians' free selection of medications because newer and more expensive patent-protected drugs are not necessarily more cost effective than or therapeutically superior to older medications.

There is no evidence in the record that Maine's use of prior authorization authority will actually harm Medicaid patients. Moreover, the State "will not subject any single-source drug that fulfills a unique therapeutic function to the prior authorization process, regardless of whether the manufacturer[] participates in [the] Maine Rx Program by entering into rebate agreements." J.A. 149. There is thus no merit to the argument that Maine Rx conflicts with the Medicaid statute because it burdens Medicaid patients.

Contrary to the views of petitioner and the United States, Maine Rx's prior authorization rule serves several Medicaid purposes. First, by making prescription drugs more affordable, more people with serious illnesses and chronic conditions will be able to treat those conditions and avoid becoming disabled and forced to go on Medicaid. Second, by subjecting more drugs to prior authorization, the Medicaid program may realize substantial cost savings as cheaper and equally effective generic drugs are substituted for branded drugs.

There is no merit to the contention that Maine's use of Medicaid prior authorization authority to [illegible]iate discounts for a non-Medicaid population violates [illegible]ute. Not only is there no such limitation in the statutory text, the United States uses its Medicaid spending to leverage discounts for a variety of federal agencies and programs that are not related to Medicaid. The sanction the Federal Government imposes when a drug manufacturer refuses to provide discounts for non-Medicaid programs is denying coverage for its drug under Medicaid. This is a far more draconian act for both patients and drug companies than Maine's prior authorization rule, which assures Medicaid patients that they will receive all medically necessary drugs regardless of whether their manufacturers participate in Maine Rx.

2. Maine Rx does not violate the dormant Commerce Clause. Maine Rx neither regulates extraterritorially nor discriminates against interstate commerce.

The extraterritoriality doctrine turns not on the location of the state law's effects, but on the location of the activity that the state law regulates or controls. A state law is unconstitutional if it applies to "commerce that takes place wholly outside the State's borders," *Edgar v. MITE Corp.*, 457 U.S.

624, 642 (1982), even if the law also nominally applies to in-state conduct. But a state law does not violate the dormant Commerce Clause simply because it both regulates in-state economic activity and affects commercial activity outside the State. Numerous important areas of state regulation, such as environmental protection or product liability law, impose additional costs on out-of-state commercial activity but are not thereby rendered unconstitutional.

Maine Rx does not violate the extraterritoriality doctrine because it does not regulate or control out-of-state activity; the program's rebates are based on the retail sale of prescription drugs at Maine pharmacies. Moreover, Maine Rx does not control the conduct of pharmaceutical manufacturers in other States; manufacturers remain free to sell their products at whatever price they can obtain. Nor does Maine Rx impermissibly link prescription drug prices in Maine to drug prices elsewhere; unlike the price-tying schemes that this Court has invalidated, Maine's program does not have the practical effect of controlling prices in other States.

Nor does Maine Rx discriminate against interstate commerce. Petitioner does not allege that Maine Rx facially discriminates or that it was adopted for a discriminatory, protectionist purpose. The program neither attempts to benefit in-state economic interests by burdening out-of-state competitors, nor to benefit Maine consumers of prescription drugs at the expense of out-of-state consumers.

The program regulates pharmaceutical manufacturers even-handedly and there is no evidence of an intent to discriminate against interstate commerce. Although the economic burden of the program could fall principally on out-of-state companies, and the benefits might inure largely to certain Maine residents, such a circumstance has never, in itself, invalidated state regulation under the Commerce Clause. *See, e.g., Exxon Corp. v. Governor of Maryland*, 437 U.S. 117 (1978).

ARGUMENT

I. THE FEDERAL MEDICAID STATUTE DOES NOT IMPLIEDLY PREEMPT MAINE FROM USING ITS PRIOR AUTHORIZATION AUTHORITY TO NEGOTIATE DISCOUNTS ON BEHALF OF ITS CITIZENS WHO LACK PRESCRIPTION DRUG COVERAGE

The court of appeals correctly held that the federal Medicaid statute, 42 U.S.C. § 1396 *et seq.*, does not preempt Maine from using its prior authorization authority to seek discounts on behalf of non-Medicaid populations who lack coverage and are thus charged the highest prices for prescription drugs. This Court should reject PhRMA's facial challenge for two reasons. First, PhRMA has failed to show that Maine's use of its prior authorization authority will conflict with Medicaid's purposes. Second, PhRMA's assertion that "Maine is holding Medicaid patients' prescription drug benefits hostage to the state's fundraising efforts on behalf of others outside the Medicaid program" and that "[s]uch leveraging necessarily conflicts with the Medicaid statute," Pet. Br. 14, is refuted by the United States' use of similar methods to obtain discounts from drug manufacturers on behalf of federal agencies and other non-Medicaid programs. *See* 42 U.S.C. § 1396r-8(a)(1), (5), (6). The judgment of the court of appeals should therefore be affirmed.

A. Maine Rx's Use Of Medicaid Prior Authorization Authority Does Not Conflict With Medicaid's Purposes

1. Congressional intent is the key to any determination that state law is preempted by federal law. *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 604-05 (1991); *see also Malone v. White Motor Corp.*, 435 U.S. 497 (1978). While Congress's intent to preempt can be either explicit or implicit, in every case the Court starts with the strong presumption

against preemption of the States' historic powers. As the Court has repeatedly stated, federal law will not preempt state law unless that is "'the clear and manifest purpose of Congress.'" *Wisconsin Public Intervenor*, 501 U.S. at 605 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Where, as here, the claim of preemption is that a state law—which is expressly authorized by the plain language of a federal statute—nonetheless conflicts with federal law because it stands as an obstacle to Congress' objectives, *see* Pet. Br. 15, the Court should be especially skeptical.

The Medicaid program is a "cooperative endeavor" between the States and the Federal Government to provide health care to certain categories of "needy" persons. *Harris v. McRae*, 448 U.S. 297, 308 (1980). "The cornerstone" of "this system of 'cooperative federalism,' . . is [a] financial contribution by both the Federal Government and the participating State." *Id.* (quoting *King v. Smith*, 392 U.S. 309, 316 (1968)). While the Medicaid statute requires that a participating State provide certain benefits under their Medicaid plan, the statute "gives the States substantial discretion to choose the proper mix of amount, scope, and duration limits on coverage" of health care. *Alexander v. Choate*, 469 U.S. 287, 303 (1985). This discretion includes whether and to what extent to provide coverage for outpatient prescription drugs. *See id.*; *see also* 42 U.S.C. § 1396d(a)(12); *id.* § 1396a(a)(54)(A). A State plan must "provide such safeguards as may be necessary to assure that . . . [covered] care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." 42 U.S.C. § 1396a(a)(19).

2. The starting point in preemption analysis is "the language employed by Congress and the assumption that the ordinary meaning of that language expresses the legislative purpose." *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740 (1985) (internal quotation and citation omitted). The relevant section of the Medicaid statute

expressly provides that "[a] State may subject to prior authorization *any covered outpatient drug*." 42 U.S.C. § 1396r-8(d)(1)(A) (emphasis added). Congress has imposed only two limitations on a state prior authorization program: 1) the program must "provide [a] response by telephone or other telecommunications device within 24 hours of a request for prior authorization," and 2) the program must "provide[] for the dispensing of at least [a] 72-hour supply of a covered outpatient prescription drug in an emergency situation." *Id.* § 1396r-8(d)(5). Maine's prior authorization program complies with these procedural safeguards. *See* Pet. App. 288a-91a. Indeed, Maine goes even further to protect Medicaid beneficiaries by authorizing a 96-hour emergency supply and by allowing pharmacists to override a prior authorization requirement and issue a one time 34-day supply of a drug. *See* Mainecare Benefits Manual § 80.07-3E.

Petitioner acknowledges that "the Medicaid statute does not expressly bar states from co-opting [*sic*] Medicaid prior authorization authority for non-Medicaid purposes." Pet. Br. 24. Notwithstanding the statute's plain and unambiguous meaning, petitioner asserts that the Maine program conflicts with the federal program because it "burdens . . . Medicaid patients, doctors, and drug company sales" and that this "is sufficient on its face to make out PhRMA's preemption case." *Id.* at 17. None of these alleged burdens establishes that the Maine programs conflicts with the objectives of Medicaid.

First, nothing in the Medicaid statute suggests that one of the Act's purposes is to protect the market share of individual drug manufacturers. Although Maine's use of prior authorization may result in manufacturers who do not participate in Maine Rx losing market share with respect to certain drugs purchased by Medicaid, their loss will become the gain of other manufacturers who participate in Medicaid. *See* 42 U.S.C. § 1396r-8(a)(1) (limiting Medicaid payment for outpatient drugs to those of manufacturers who enter into rebate agreements with the Federal Government). Moreover, as the

affidavit of Dr. Clifford indicates, where a single-source drug "fulfills a unique therapeutic function," it will not be subject to prior authorization regardless of whether the manufacturer participates in Maine Rx. J.A. 149 (Clifford affidavit at ¶ 9).

Second, the prior authorization rule does not unreasonably burden physicians. Prior authorization rules are a common feature of both public and private health care benefit plans with which physicians are very familiar. *See, e.g., Rush Prudential HMO, Inc. v. Moran*, 122 S.Ct. 2151, 2156 (2002); *see also* J.A. 149 (Clifford affidavit at ¶ 11). Indeed, the Medicaid programs of thirty-five States and the District of Columbia impose prior authorization requirements for prescription drugs. Renee Schwalberg *et al.*, Kaiser Commission on Medicaid and the Uninsured, *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights* 6 (2001).

Moreover, independent of the Maine Rx program, Maine has imposed prior authorization on more than 400 different drugs and dosages that are covered by Medicaid.[5] *See* Maine Medicaid Prior Authorization List, http://www.ghsinc.com/Japps/upload/PA_List_10.01.02xls/ (visited October 2, 2002). In addition to internet posting of the prior authorization list, the State mails the list to prescribers "at least quarterly." Mainecare Benefits Manual, Ch. II, § 80.05-3I. Physicians who treat Maine Medicaid patients can thus readily determine whether a drug is subject to prior authorization. Furthermore, Maine has initiated a program under which primary care "[p]roviders who have consistently prescribed in a cost effective manner have been offered exemptions in various [prior

[5] Of the top fifty drugs by retail sales volume in 2001, thirty-five are on the Maine Medicaid program's prior authorization list. *Compare Prescription Drug Expenditures In 2001, supra*, at 13 (Table 3), with Maine Medicaid Prior Authorization List. Of the fifteen top-selling drugs that are not on Maine's current prior authorization list, four of the drugs are generics, three are antibiotics, and three are hormones.

authorization drug] categories." Maine Department of Human Services, *Pharmacy Update* 2 (Fall 2001). Petitioners have thus failed to show that the Maine Rx prior authorization rule is so burdensome to physicians that it violates the Medicaid statute's goal of providing care and services "in a manner consistent with simplicity of administration." 42 U.S.C. § 1396a(a)(19).

Petitioner further contends that "[t]he prior authorization process interferes with the physician's free selection of medications to treat his or her Medicaid patient, forcing the physician to choose between a first-choice drug that requires prior authorization and a second-choice, possibly less effective, drug that does not." Pet. Br. 15. This speculative hypothesis does not establish that the State's use of prior authorization conflicts with the Medicaid program's goals. Frequently, a "second-choice" drug will produce favorable results in a patient and at a far lower price.[6]

Indeed, as a leading health-care economist explains, there is "a growing stream of new, 'me-too' medications . . . that typically cost twice or three times as much as the drugs they replace. And neither the medical profession nor insurers have

[6] Petitioners do not define the terms "first-choice" and "second-choice" drug. *Amici* note, however, that many drugs that are considered state-of-the-art have lost or will soon lose patent protection. *See* Milt Freudenheim, *Ruling Backs Some Patents on a Leading Ulcer Drug*, N.Y. Times, Oct. 12, 2002, at C14 (noting holding of federal district court that generic version of Prilosec made by Schwarz Pharma did not infringe Astra Zeneca's patents and that "Astra Zeneca is trying to persuade doctors to switch patients from Prilosec to a similar successor drug, Nexium"). For example, a physician treating depression can prescribe either Prozac or its generic equivalent—fluoxentine. While petitioner would likely deem Prozac to be a "first-choice" drug—indeed, it is still considered state of the art—fluoxentine is far cheaper and is therapeutically equivalent to Prozac. Petitioner's terms do not explain whether the generic competitors to leading branded drugs are first-choice or second-choice therapies.

shown much interest in finding out if the higher-priced drugs offer commensurately superior benefits." Uwe E. Reinhardt, *How to Lower the Cost of Drugs*, N.Y. Times, Jan. 3, 2001, at A17; *see also* Stephen S. Hall, *The Claritin Effect: Prescription for Profit*, N.Y. Times Magazine, Mar. 11, 2001, at 40, 42 ("Studies sponsored by drug companies tend to show an advantage for the company's own products."). Moreover, a "first-choice" drug may have a side-effect risk profile that is unsuitable for a particular patient or be contra-indicated because of the patient's condition or other drugs being taken by a patient. *See* J.A. 150 (Clifford affidavit ¶ 12).

Finally, and most importantly, neither petitioner nor the United States has shown that Maine's rule will be enforced in a manner that unreasonably burdens Medicaid patients or that it lacks the "safeguards . . . necessary to assure" that prescription drugs will be made available in "a manner consistent with 'the best interests of [Medicaid] recipients.'" U.S. Br. 19 (quoting 42 U.S.C. § 1396a(a)(19)); *see also* Pet. Br. 17. Petitioner's argument that Medicaid patients will be denied drugs prescribed by their doctors and "find themselves . . . without the means to navigate the prior authorization bureaucracy," *id.*, incorrectly assumes that neither physicians nor pharmacists will assist their patients. Moreover, Maine expressly authorizes a pharmacist "to provide a 96-hour supply" of a covered drug in an emergency, Mainecare Benefits Manual, § 80.07-3D, and "a one-time 34-day supply of the prescribed drug" where the "prescriber fails to submit" the form for requesting authorization. *Id.* § 80.07-3E.

Petitioner further contends that Medicaid patients "may be put through trial-and-error routines on second-choice drugs in order to prove that they need a drug subject to prior authorization" and suggests that this unreasonably risks the health of Medicaid patients. Pet. Br. 17. But even "first-choice" drugs may not be effective in a particular patient and may result in trial-and-error treatment. *See* Hall, *The*

Claritin Effect, *supra*, at 40-42 (noting opinion of two allergy specialists, one of whom believed Claritin was effective in 50 to 55 percent of patients, the other believing that 30 to 40 percent of patients who tried drug benefited). Moreover, a "first-choice" drug might nonetheless cause adverse side effects in a patient.[7] *See, e.g.*, *Physicians' Desk Reference* 2221 (56th ed. 2002) (noting that anti-cholesterol drug "Zocor is contraindicated during pregnancy and in nursing mothers" as well as for patients with "active liver disease" and may cause myopathy); *id.* at 2754 (Table 2) (reporting side effects experienced by patients taking Zoloft in clinical trials which included nausea by 27 percent, diarrhea by 21 percent, insomnia by 22 percent, somnolence by 14 percent, and dizziness by 12 percent).

Finally, state Medicaid plans have long imposed prior authorization requirements on their coverage of prescription drugs and these rules have undoubtedly been applied to numerous Medicaid patients. *See* U.S. Br. 14-15, 18. Nonetheless, petitioner has failed to produce any evidence of actual harm to patients and expressly declined to do so.[8] *See* Pet.

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[7] It is estimated that between 25 to 60 percent of all prescriptions are for non-FDA approved or "off-label uses." James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 Food & Drug L. J. 71, 80 (1998). While such use is commonplace and accepted in the medical community, "[e]xamples of off-label uses that have serious medical risks abound," such as the recalled diet drug Fen/phen. *Id.* at 72 n.6 (citing 62 Fed. Reg. 64,080-81). Prior authorization can protect patient safety by ensuring that a prescription for an off-label use is medically appropriate and supported by medical research.

[8] In its lodging, petitioner included a newspaper article relating the story of a Medicaid patient who suffered side effects when taken off of Prilosec because of the State's decision to subject that drug to prior authorization. *See* Pet. Lodging at 20. The factual allegations therein are neither part of the record nor judicially noticeable. *See* Fed. R. Evid. 201(b).

Br. 17. There is thus no merit to the argument that Maine Rx conflicts with the Medicaid statute because it burdens Medicaid patients, physicians, and drug companies.

B. The Maine Rx Prior Authorization Rule Serves Medicaid-Related Goals

The United States and petitioner argue that Maine Rx's use of Medicaid prior authorization authority to seek discounts for the uninsured violates the federal statute because it does not serve a Medicaid-related purpose. *See* Pet. Br. 18-19, 24-26; U.S. Br. 18-22. While acknowledging "[a] State's broad power to subject drugs to a prior authorization requirement," the United States asserts that "the Act contains a further limitation that a State will not use Medicaid's prior authorization provisions in order to further goals unrelated to the Medicaid program." U.S. Br. 18. The Court should reject these arguments, which erroneously assume that Maine's use of prior authorization does not serve Medicaid-related goals. As explained below, Maine's broader use of prior authorization advances Medicaid goals in several ways. Moreover, these arguments ignore that the United States uses its Medicaid spending to leverage discounts for non-Medicaid participants in other federal programs.

First, because Maine Rx will increase access to medicines that prevent, ameliorate or cure disabling illnesses and chronic conditions, fewer members of the State's non-Medicaid population will suffer disabling medical conditions that result in the loss of income and force them onto Medicaid. As the court of appeals recognized, "[w]hen people whose incomes fall outside Medicaid eligibility are unable to purchase necessary medication, their conditions may worsen, driving them further into poverty and into the Medicaid program, requiring more expensive treatment that could have been avoided had earlier intervention been possible." Pet. App. 13a.

Indeed, petitioner and its members have repeatedly touted the cost savings of their products compared with surgical procedures and hospitalization. For example, one of petitioner's publications notes that "[t]he annual cost of drug therapy [for schizophrenia] was $4,500, compared to more than $73,000 for treatment in a state mental hospital." PhRMA, *The Value of Medicines* 17 (2002); *see also id.* at 14 ("A single hip fracture costs an estimated $41,000, while treatment with a leading hormone replacement medicine that has been shown to prevent osteoporosis costs $730 annually."); *id.* at 19 ("The lifetime cost of a stroke exceeds $100,000 per patient, while the average annual cost of treatment with a blood-thinning drug, including monitoring, is $1,025.").[9]

Unfortunately, "[t]he financial effects of heart attacks and strokes, progressively worsening asthma, or cancer only may begin with medical bills. Such medical problems may leave a wage earner with a sharply reduced or nonexistent earning capacity." *See generally* Melissa B. Jacoby *et al.*, *Rethinking The Debates Over Health Care Financing: Evidence From The Bankruptcy Courts*, 76 N.Y.U. L. Rev. 375, 407 (2001). Thus, a major illness or chronic condition can result in economic devastation even for those who earn more than three times the poverty line.[10] *See id.* at 377 (estimating "that

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[9] Petitioner has also asserted that the "[u]se of cholesterol-lowering medicine reduced hospitalizations and the need for bypass surgery and angioplasty." *The Value of Medicines*, *supra*, at 19; *see also* Pfizer, *Pfizer's Lipitor® Showed Significant Benefit In Reducing Heart Attacks And Stroke*, Oct. 10, 2002 (*available at* http://www.pfizer.com/pfizerinc/about/press/lipitor1010.html). The average cost of bypass surgery is $45,000. *See* John Morgan, *Robotics revolutionizing heart bypass*, U.S.A. Today, Feb. 29, 2000 (*available at* http://www.usatoday.com/lief/health/doctor/1hdoc101.htm).

[10] This is the cutoff for participation in the Maine demonstration project, which the Secretary of HHS has approved as "'likely to assist in

more than half a million middle-class families turned to the bankruptcy courts for help following a[n] illness or injury in 1999"). By reducing the number of persons who suffer disabling illnesses and are forced to go on Medicaid, the Maine Rx program will achieve significant cost-savings for the Medicaid program.

Second, Maine's use of its prior authorization authority may well result in additional cost savings for the Medicaid prescription drug program. As a result of Maine Rx, the State will scrutinize more drugs prior to their dispensing. That action will result in substantial cost savings to the Medicaid program as cheaper and equally effective generic drugs are substituted for branded drugs.

Moreover, because doctors' prescribing decisions may be influenced by drug manufacturers' marketing skills rather than by scientific fact, the Medicaid program may realize additional cost savings by substituting older and cheaper drugs for newer "me—too" drugs that offer no therapeutic advantage. Reinhardt, *How to Lower the Cost of Drugs*, *supra*, at 17. *See also* Hall, *The Claritin Effect*, *supra*, at 42

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promoting the objectives' of the Medicaid program." U.S. Br. 21 (quoting 42 U.S.C. § 1315(a)).

Both the United States and petitioner argue that the Maine Rx program should be invalidated because it is open to all Maine residents. *See* U.S. Br. 22 (noting that "Maine Rx . . . targets persons whose income is in excess of 300% of the federal poverty level[,]" and that "[n]o Medicaid-related purpose is served by a state program focusing on that population"); *see also* Pet. Br. 25 ("The Maine Rx program, which is open to all Maine residents rich or poor, is not, and could not pass muster as, a demonstration project."). It is, however, unlikely that large numbers of wealthy or upper middle class individuals will enroll in the Maine Rx program because it is not an insurance plan. While the program results in lower drug prices, enrollees must pay for their drugs out of their own pocket. Wealthy and upper middle class individuals are thus unlikely to enroll in the plan as they are either covered by their employer's plan or can purchase their own insurance.

(noting that company-sponsored studies "serve as marketing tools, providing drug-company salesmen with their best lines"); Melody Petersen, *Merck Is Said To Limit Perks In Marketing To Physicians*, N.Y.Times, Jan. 18, 2002, § C, at 1 (noting drug manufacturers' "common practice" of providing physicians with "free Broadway plays, weekend trips and other gifts"). To the extent that the Maine Rx rule results in the Medicaid program realizing additional cost savings, Medicaid patients will benefit because the State will be able to maintain a higher level of coverage.

The Maine Rx rule thus clearly serves several Medicaid purposes. *See* U.S. Br. 15 ("subject[ing] covered drugs to prior authorization in order to achieve cost savings for the Medicaid program . . . would further Congress's specific intent"). The fact that it also serves another objective by reducing prescription drug prices for Maine's uninsured citizens does not create an impermissible conflict with the federal scheme.

Finally, notwithstanding the absence of any supporting language in the Medicaid statute's text, the United States and petitioner contend that the act's structure and purpose prohibit Maine from using its prior authorization authority to negotiate discounts for a non-Medicaid population. *See* Pet. Br. 24-25; U.S. Br. 19. According to the United States, "Congress presumably did not intend that a State would leverage its Medicaid program to force a drug manufacturer to fund the State's transportation or education systems." *Id.*; *see also* Pet. Br. 14 ("Maine is holding Medicaid patients' prescription drug benefits hostage to the state's fundraising efforts on behalf of others outside the Medicaid program. Such leveraging necessarily conflicts with the Medicaid statute."). Maine does not, however, seek drug discounts to fund non-health related state programs, but rather to lower the price of prescriptions to make them more affordable for those without drug coverage.

Most significantly, the foregoing contention ignores that the United States uses its Medicaid spending to leverage discounts from drug manufacturers for a variety of federal agencies and programs. [11] A number of these programs impose no income limitation (or an income limitation in excess of 300% of the poverty line) on their patients. *See* 42 U.S.C. § 1396r-8(a)(1), (5), (6); *id.* § 256b(a)(4); 38 U.S.C. § 8126. Under these provisions, a drug manufacturer must, as a condition of Medicaid coverage of their drugs, also agree to provide rebates for drugs purchased by the Defense Department, Coast Guard, Public Health Service, Department of Veterans Affairs, and other covered entities under Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.[12]

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[11] The Medicaid program accounts for 11 percent of prescriptions sold at retail pharmacies. *See Report to the President*, *supra*, at 99 (Figure 3-1).

[12] Veterans who are enrolled in the VA's Medical Benefits Package can receive prescriptions for a modest copayment. In fiscal year 2000, "approximately 1.1 million veterans averaged 47 30-day supply prescriptions per year" through the program. Copayments for Medications, 66 Fed. Reg. 36960, 36962 (2001) (codified at 38 C.F.R. § 17.110). While the VA does impose a means test, the test is used solely to determine whether a veteran must pay the $ 7 per prescription copayment. *See id.* at 36961; *see also* 38 C.F.R. § 17.36(b)(7).

Under the Department of Defense's TRICARE program, dependents of active-duty and retired service members, as well as retired members can obtain prescription drugs for limited copayments, which vary depending upon where they fill their prescription. Indeed, if the person fills the prescription at a military treatment facility, there is no copayment for either a generic or branded drug. The program does not employ a means test. *See* Assistant Secretary of Defense (Health Affairs) & TRICARE Mgmt. Activity, *Pharmacy Co-Pays, available at* http://www.tricare.osd.mil/pharmacy/newcopay.cfm.

Similarly, non-Medicaid patients of programs covered by the Section 340B drug pricing program, 42 U.S.C. § 256b(a)(1), can receive prescription drugs "as long as they are patients of the covered entity." Office of Pharmacy Affairs, *Overview and Frequently Asked Questions 340B—Drug Pricing Program* 3 (available at http://bphc.hrsa.gov/opa/faqs.htm).

The Federal Government's policy of denying Medicaid coverage for a manufacturer's drugs is a draconian sanction that is likely to have a far greater impact on a manufacturer's market share than Maine's use of prior authorization. The federal policy also could have far more deleterious consequences for the health of Medicaid patients than Maine's prior authorization rule—Maine's rule assures Medicaid patients that they will receive all medically necessary drugs regardless of whether their manufacturers participate in Maine Rx. *See* J.A. 149 (Clifford affidavit at ¶ 9). That Congress nonetheless imposed this requirement refutes the United States' and petitioner's contention that the structure and purpose of the statute limit a State's authority to use its Medicaid spending to benefit non-Medicaid populations.

As the foregoing demonstrates, the limitation which the United States and petitioner seek to impose on Maine finds no support in Medicaid's statutory text. Nor can it be implied from the statute's structure and purpose. Medicaid is a cooperative federal-state program in which Maine spends substantial sums on its Medicaid prescription drug benefit ($107.5 million in fiscal year 1999). *See* J.A. 182. Simultaneously, Congress uses its Medicaid spending to leverage discounts for unrelated federal health programs. Under these circumstances, the creation of any such limitation on the States' use of Medicaid prior authorization authority should be left to Congress, which can, if it sees fit, explain to state officials why a policy that is valid for the Federal Government is off-limits to the States.

For example, seventeen of the AIDS Drug Assistance Programs authorized by the Ryan White CARE Act have income eligibility limits greater than 300 percent of the federal poverty line; three of the programs have income limits of 500 percent or greater. *See* Health Resources and Services Administration, *AIDS Drug Assistance Programs (ADAPs) Eligibility Criteria* 1-2 (May 2001).

II. MAINE Rx DOES NOT VIOLATE THE DORMANT COMMERCE CLAUSE

The Maine Rx program does not violate the dormant Commerce Clause. Although Maine's program might well affect commercial activity occurring in other States, it does not regulate or effectively control out-of-state conduct. Nor does Maine Rx impermissibly link prescription drug prices in Maine to drug prices elsewhere; unlike the price-tying schemes that this Court has previously invalidated, Maine's program does not have the practical effect of controlling prices in other States. Moreover, Maine Rx does not discriminate against interstate commerce. Although the economic burden of the program could fall principally on out-of-state companies, and the benefits might inure largely to certain Maine residents, such a circumstance has never, in itself, invalidated state regulation under the Commerce Clause.[13]

A. Maine Rx Does Not Regulate Extraterritorially

It is well established that a State "has no power to project its legislation into [another state] by regulating the price to be paid in that state for [goods] acquired there." *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935). Thus, a State may not apply its own law to "commerce that takes place wholly outside of the State's borders." *Edgar v. MITE Corp.*, 457 U.S. 624, 642 (1982) (plurality opinion). Nor may a State "directly control[] commerce occurring outside [its] boundaries," even when the regulation nominally applies only to in-state conduct. *Healy v. Beer Institute*, 491 U.S. 324,

[13] Unless figures in Maine deviate substantially from nationwide statistics, Maine Rx will potentially affect the sale of prescription drugs to considerably less than one-third of Maine's residents. Nationwide, 65% of retail drug sales are to consumers enrolled in a prescription drug plan managed by a third-party pharmacy benefit manager who negotiates discounts on prescription drug retail prices. *See* discussion *supra* at 3. Medicaid covers an additional 11% of prescription drug sales nationwide. *See* note 11, *supra*.

336 (1989). As this Court recognized in *Healy*, the "critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Id.*

At the same time, a state law is not unconstitutional simply because it *affects*—even substantially—commercial activity occurring outside the state. *See* Jack L. Goldsmith & Alan O. Sykes, *The Internet and the Dormant Commerce Clause*, 110 Yale L.J. 785, 803 (2001) ("State regulations are routinely upheld despite what is obviously a significant impact on outside actors."); Donald H. Regan, *Siamese Essays: (I) CTS Corp. v. Dynamics Corp. of America and Dormant Commerce Clause Doctrine; (II) Extraterritorial State Legislation*, 85 Mich. L. Rev. 1865, 1874 (1987) ("the mere fact that a statute has extraterritorial effects does not raise an extraterritoriality problem"). Numerous areas of state law—such as environmental protection, product liability, obscenity, and consumer protection, to name a few—plainly impose additional costs on commercial activity taking place in other States. This Court has never suggested that such extraterritorial effects, standing alone, are sufficient to constitute a violation of the dormant Commerce Clause.

Thus, extraterritoriality questions under the Commerce Clause turn not on the location of the state law's effects, but on the location of the activity that the state law regulates or effectively controls. And Maine Rx regulates or controls only activity that occurs within Maine's borders: the retail sale of drugs at Maine pharmacies. A manufacturer that enters a rebate agreement with the State will not be obligated to make any payments under the program unless its drugs are actually sold in Maine.

Petitioner repeatedly asserts that the State is "regulating wholesale sales by manufacturers that take place wholly outside of Maine," Pet. Br. 27, but no consequences whatsoever flow from a manufacturer's out-of-state wholesaling activity. Petitioner's argument confuses the *target* of the

regulation—here, the pharmaceutical manufacturers—with the conduct that the program regulates. Many state laws target out-of-state actors while permissibly regulating only in-state conduct. For example, state tort law imposes liability on wholly out-of-state manufacturers, but the activity being regulated is the use of the manufacturers' products within the State's borders.

State laws are impermissibly extraterritorial only when they regulate or control out-of-state activity. For example, the law at issue in *Brown-Forman Distillers Corp. v. New York State Liquor Auth.*, 476 U.S. 573 (1986), required liquor distillers and producers to file advance price schedules each month and affirm that they would not sell at lower prices anywhere in the United States. *Id.* at 575–76. The law regulated extraterritorially because, once a distiller or producer had filed its prices with the State, New York law effectively controlled what prices could be charged in other States. *Id.* at 582–83. It regulated the terms of transactions occurring wholly outside New York.

The same was true in *Healy*, which involved a similar price affirmation scheme. *See* 491 U.S. at 326–29. That law prohibited beer distributors from contemporaneously selling their products in Connecticut at prices higher than those they were charging in surrounding States. *Id.* As in *Brown-Forman*, the law had "the undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State," for once the prices had been posted, Connecticut law forbade sales at lower prices in other States. *Id.* at 337.

Maine Rx, in contrast, exerts no such control over out-of-state conduct. First, Maine's program, by its terms, does not directly regulate any conduct occurring outside the State. Second, Maine Rx does not have the "practical effect" of controlling the conduct of pharmaceutical manufacturers in other States. Unlike the laws in *Brown-Forman* and *Healy*, nothing in Maine Rx dictates the terms on which drug

manufacturers must sell their drugs to wholesalers in other States. The manufacturers remain free to sell their products at whatever price they can obtain.[14]

To be sure, Maine's program may well impose additional costs on out-of-state activities (or reduce the profits that those activities generate), and thus *affect* the price terms of commercial transactions occurring in other States. But the same is true of many state laws that have never raised Commerce Clause concerns. For instance, Maine product liability law might substantially increase drug manufacturers' costs of doing business. Indeed, Maine tort law might have a significant impact on the price of the manufacturers' insurance premiums—insurance that they purchase through wholly out-of-state transactions with their carriers. But these extraterritorial effects would not render Maine's product liability law unconstitutional, even if the manufacturers' "only link to the state is that the goods flow through a stream of interstate commerce that the manufacturers do not control and ultimately come to rest on a pharmacy counter in Maine." Pet. Br. 28. Because Maine's tort law would not have the practical effect of controlling out-of-state conduct, it would not violate the Commerce Clause's extraterritoriality principle.[15]

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[14] Petitioner raises the specter of Maine demanding rebates from "any manufacturer of any product located anywhere in the country," such as oil refiners in Texas or semiconductor manufacturers in California. *See* Pet. Br. 30. Such measures would likely be unconstitutional, either because they singled out products for discriminatory reasons, *see Bacchus Imports, Ltd. v. Dias*, 468 U.S. 263 (1984), or because they unduly burdened interstate commerce, *see Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).

[15] Petitioner suggests that Maine Rx "resembles a sales tax," Pet. Br. 31, and is unconstitutional because it fails the "substantial nexus" prong of the four-part test of *Complete Auto Transit, Inc. v. Brady*, 430 U.S. 274 (1977). *See* Pet. Br. 31–32. The simple response is that if the program's rebate payments are properly characterized as taxes, this case must be dismissed for want of jurisdiction because petitioner sought injunctive relief and has made no showing that Maine does not provide "a plain,

Nor does Maine Rx impermissibly link drug prices in Maine to the prices that drug manufacturers can charge in other States. What rendered the laws in *Brown-Forman* and *Healy* unconstitutional was that, by requiring that the posted prices be the lowest offered by the sellers anywhere, they had the "undeniable effect of *controlling*" prices in other States. *Healy*, 491 U.S. at 337 (emphasis added). Such price-tying schemes plainly project a State's legislation into other States; they make it a violation of State A's laws to sell goods below a certain price in State B.

Maine Rx has no similar effect. True enough, the program directs the commissioner to use his "best efforts to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medicaid program," 22 Me. Rev. Stat. § 2681.4.B, an amount that is based in part on the prices that the manufacturers charge throughout the country, *see* 42 U.S.C. § 1396r–8(c)(1). But a State's looking to out-of-state prices as a basis for negotiating its own rebates—essentially engaging in a form of market research—is fundamentally different from a state scheme that effectively *controls* prices elsewhere. A manufacturer's rebate agreement under Maine Rx does nothing to constrain that manufacturer's pricing decisions in other States or in the majority of transactions in Maine itself. *See* note 13, *supra*. No aspect of any out-of-state transaction could violate Maine's law.

Again, Maine Rx might affect commercial transactions occurring wholly outside the State. Indeed, Maine's program

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speedy and efficient remedy" in its own courts. 28 U.S.C. § 1341; *see also California v. Grace Brethren Church*, 457 U.S. 393, 408 (1982). Consequently, if Maine Rx actually imposes a sales tax, the district court did not have jurisdiction in the first instance, and this Court lacks jurisdiction as well. *See Franchise Tax Bd. v. Alcan Aluminium Ltd.*, 493 U.S. 331 (1990) (ordering that case be dismissed after concluding it was barred by Tax Injunction Act); *Rosewell v. LaSalle Nat'l Bank*, 450 U.S. 503 (1981) (same).

might "alter[]" the drug manufacturers' "out-of-state pricing calculations," just as petitioner alleges. Pet. Br. 33. But such an effect, in itself, raises no extraterritoriality concerns under the Commerce Clause.

B. Maine Rx Does Not Discriminate Against Interstate Commerce

Petitioner lastly contends that Maine Rx impermissibly discriminates against interstate commerce "because it externalizes the costs and internalizes the benefits of the program." Pet. Br. 35.[16] As an initial matter, it is important to clarify what petitioner is *not* alleging—namely, that Maine Rx facially discriminates against interstate commerce, or that the State adopted the program with a discriminatory, protectionist purpose. Maine Rx regulates pharmaceutical manufacturers evenhandedly, and there is no evidence of an intent to discriminate against interstate commerce. Thus, Maine Rx could violate the Commerce Clause's nondiscrimination principle only if it discriminated against interstate commerce "in practical effect." *See, e.g., Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333 (1977). Petitioner asserts that Maine Rx does so, relying almost exclusively on *West Lynn Creamery, Inc. v. Healy*, 512 U.S. 186 (1994). This claim fails for at least three reasons.

First, *West Lynn* involved the quite different circumstance of a state law that was plainly protectionist in its purpose and effect. In *West Lynn*, Massachusetts had adopted a milk pricing order that imposed a tax on all milk dealers in the State, and then used the tax's proceeds exclusively to

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[16] Petitioner's assertion that Maine Rx forces pharmaceutical companies to externalize costs is, at best, premature as there is no evidence in the record that Maine Rx will necessarily lead to lower profits. As long as rebates negotiated under Maine Rx do not force pharmaceutical companies to sell prescription drugs in Maine at a loss, drug company profits from pharmaceutical sales in Maine could in fact increase due to higher demand resulting from lower, but still profitable, prices.

subsidize Massachusetts dairy farmers. *See id.* 190-91. The pricing order thus operated as a tax "effectively imposed only on out-of-state products," permitting "Massachusetts dairy farmers who produce at higher cost to sell at or below the price charged by lower cost out-of-state producers." *Id.* at 194-95. As this Court recognized, the "avowed purpose" and the "undisputed effect" of the order were protectionist: "to enable higher cost Massachusetts dairy farmers to compete with lower cost dairy farmers in other States." *Id.* at 194. The Massachusetts law was therefore unconstitutional.

Maine Rx, in contrast, has no such protectionist purpose or effect. The program attempts neither to "benefit in-state economic interests by burdening out-of-state competitors," *New Energy Co. v. Limbach*, 486 U.S. 269, 273-74 (1988), nor to benefit Maine consumers of prescription drugs at the expense of out-of-state consumers, *cf. Kassel v. Consolidated Freightways Corp.*, 450 U.S. 662 (1981) (invalidating state limit on truck lengths that benefited in-state highway users at the expense of out-of-state highway users). Of course, the program aims to confer the benefit of lower prescription drug prices on those Maine residents who lack collective purchasing power. *See* discussion *supra* at 3-5. But that does not render the program protectionist in purpose or effect.[17]

Second, a state law is not discriminatory merely because the burden of the regulation falls largely (or even exclusively) on out-of-state interests. *See, e.g., Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456 (1981); *Exxon Corp. v. Governor of Maryland*, 437 U.S. 117 (1978). For example, *Exxon* involved a Maryland statute that prohibited any producer or refiner of petroleum products from operating a retail service station in the State. 437 U.S. at 119. Because

[17] It is also significant that the pricing order invalidated in *West Lynn* consisted of both a tax and a subsidy. If the Maine Rx rebates are properly viewed as taxes, then the Court should dismiss the case for lack of jurisdiction under the Tax Injunction Act. *See* note 15 *supra*.

no petroleum producers or refiners were located in Maryland—just as no pharmaceutical manufacturers are located in Maine—the burden of the regulation fell exclusively on out-of-state companies. *Id.* at 125. In addition, 99 percent of the "independent dealers" that were effectively insulated from the regulation were in-state companies. *Id.* at 138 (Blackmun, J., dissenting).

This Court nonetheless concluded that the statute did not discriminate against interstate commerce. *Id.* at 125-26. "The fact that the burden of a state regulation falls on some interstate companies does not, by itself, establish a claim of discrimination against interstate commerce." *Id.* at 126. Instead, what matters is the regulation's impact on interstate markets: "If the effect of a state regulation is to cause local goods to constitute a larger share, and goods with an out-of-state source to constitute a smaller share, of the total sales in the market . . . the regulation may have a discriminatory effect on interstate commerce." *Id.* at 126 n.16. Because the Maryland statute had no such effect, there was no discrimination against interstate commerce. The same is true of Maine Rx. While the burden of the regulation may fall largely on out-of-state pharmaceutical manufacturers, *but see* note 16, *supra*, petitioner has not contended that the program alters the respective market shares of in-state and out-of-state products. Nor *could* petitioner make such a claim, as there are no Maine manufacturers to protect. Maine Rx thus does not discriminate against interstate commerce as this Court has defined the concept.

Finally, petitioner's discrimination claim rests on the type of "cost externalization" analysis that this Court has expressly disavowed in adjudicating dormant Commerce Clause disputes. In *Commonwealth Edison Co. v. Montana*, 453 U.S. 609 (1981), the plaintiffs challenged Montana's coal severance tax, contending that because 90 percent of the coal mined in Montana was consumed outside the State, the tax

imposed its economic burden primarily on out-of-state consumers and thus discriminated against interstate commerce. *Id.* at 617-18. They argued that while Montana residents enjoyed the full benefit of the tax's revenue, almost all of its costs were felt outside the State.

This Court rejected the claim. First, because the tax made no distinction as to where the coal was consumed, there was "no real discrimination in this case; the tax burden [was] borne according to the amount of coal consumed and not according to any distinction between in-state and out-of-state consumers." *Id.* at 619. The same logic applies to Maine Rx. The size of the rebates depends solely on the amount of the drugs sold in Maine by each manufacturer to Maine Rx participants; all pharmaceutical companies are treated even-handedly, regardless of location. More generally, the Court in *Commonwealth Edison* expressed its "misgivings about judging the validity of a state tax" based on a State's alleged "'exportation' of the tax burden out of State." *Id.* at 618. The same misgivings should give the Court pause here.

In short, asserted "cost exportation" by a state regulation, without more, does not violate the Commerce Clause. Indeed, the rule urged by petitioner—that any state law that confers its benefits exclusively on that State's residents but which disproportionately burdens out-of-state economic interests is, for that reason, unconstitutional—could have far-reaching implications, jeopardizing wide areas of traditional state regulation. There is no warrant for such an expansion of this Court's dormant Commerce Clause doctrine.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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